

REMARKS

Claims 1, 2, 4 and 8 have been amended, and claims 1-10 are pending.

In an abundance of caution and to be perfectly clear, applicants have renamed the flanking regions of the capture probes recited in claim 4 as R₃ and R₄, respectively, since R₁ and R₁ are used in claim 1, from which claim 4 depends.

Applicants respectfully request reconsideration of the application in view of the foregoing amendments and in view of the reasons that follow.

I. REJECTIONS UNDER 35 U.S.C. § 112 ¶1

The examiner rejects claim 4 for allegedly failing to convey to the skilled person that the applicants possessed the claimed invention at the time the application was filed. Applicants respectfully traverse the rejection.

Claim 4 is directed to a method of detecting the presence of quinolone resistant *E. coli* strains using a micro-array with, *inter alia*, at least one set of capture probes derived from the sequence of a parC gene. In particular, the claim defines the capture probes by the sequence R₃-(Y)-R₄, wherein Y designates all permutations of the triplet at amino acid position 80, 84 or 87 of the parC polypeptide of *E. coli*. Thus, contrary to the examiner's assertion, the claim defines the genus of capture probes solely by structure. Moreover, by defining Y as designating all permutations of the triplet at amino acid position 80, 84 or 87 of the parC polypeptide, the claim effectively identifies every species within the claimed genus. Thus, one of skill in the art would readily recognize that, as of the filing date, applicants possessed the claimed invention.

Accordingly, applicants request that the rejection be withdrawn.

II. REJECTIONS UNDER 35 U.S.C. § 112 ¶2

The examiner rejects claims 1-10 for alleged indefiniteness. In particular, the examiner asserts that it is unclear whether claims 1 and 4 require one or two sets of capture probes. Applicants believe the present amendments obviate the rejection. Support for the amendments can be found at, for example, ¶¶ 36 & 40.

The examiner also asserts the claim 8's reference to Table 1 renders the claim unclear. Applicants believe the present amendments obviate the rejection.

The examiner asserts that term “nucleic acid” lacks antecedent support. Applicants believe the present amendments obviate the rejection.

III. REJECTIONS UNDER 35 U.S.C. § 103

The examiner rejects claims 1-3, 5, 6, 8-10 under 35 U.S.C. §103(a) for allegedly being unpatentable over Weigel et al. (WO 99/50458) in view of Chee et al. (A) (WO 95/11995) and Alberts et al. (Molecular Biology of the Cell). Applicants respectfully traverse the rejection.

In levying an obviousness rejection under 35 U.S.C. 103, the examiner has the burden of establishing (1) some suggestion or motivation to modify the reference or to combine reference teachings, (2) a reasonable expectation of success, and (3) that the prior art references, when combined, teach or suggest all the claim limitations. *See* MPEP §2143 (May 2004). “Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant’s disclosure.” *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438 (Fed. Cir. 1991). In the pending case, the examiner has failed to satisfy this burden.

Weigel teaches a variety mutations associated with quinolone resistance in *Enterobacteriaceae*. In particular, Weigel notes that codons 81, 83 and 87 of *gyrA* are often mutated in fluoroquinolone-resistant strains of *Enterobacteriaceae*. *See* Weigel, pg. 3, ln. 3-8; Figures 4A-B. Contrary to the examiner’s assertion, however, Weigel does not teach or suggest that quinolone resistance in *E. coli* can be determined effectively simply by assessing in a single assay the mutational status of residues 83 and 87. Moreover, Weigel does not suggest assaying for all possible permutations of nucleotides for the codons at these positions. In fact, and contrary to the examiner’s assertion, the cited portions of Weigel reveal only a single mutant codon at residue 83 (i.e., Leu (TTG)) and three mutant codons for residue 87 (i.e., Gly (GGA); Tyr (TAC); Asn (AAC)). Similarly, with respect to claim 3, the cited portions of Weigel are silent as to quinolone-resistance changes at residues 85 and 89.

The secondary references do not cure the defects of the primary reference. Neither Chee (A), cited for teaching an array of capture probes, nor Alberts, cited for teaching all possible combinations of nucleotides for a codon, teach or suggest that quinolone resistance

can be determined in *E. coli* simply by assessing in a single assay the mutational status of residues 83 and 87. Thus, no combination of the cited references presages the claimed invention.

The examiner also rejects claim 7 under 35 U.S.C. §103(a) for allegedly being unpatentable over Weigel et al. (WO 99/50458), Alberts et al. (Molecular Biology of the Cell) and Chee et al. (A) (WO 95/11995) in view of Chee et al. (B) (*Science* 1996) and Routier (*Nucleic Acids Research* 1999). Applicants respectfully traverse the rejection.

Claim 7, which depends from claim 1, adds the limitation that the DNA is “fragmented to pieces having a length of from about 10 to about 40 nucleotides.” The limitations of Weigel, Alberts and Chee (A) are discussed above. Neither of the additional references teach or suggest that quinolone resistance can be determined in *E. coli* simply by assessing in a single assay the mutational status of residues 83 and 87. Thus, no combination of the cited references presages the claimed invention.

Accordingly, since the examiner has failed to establish a *prima facie* case of obviousness, the rejections should be withdrawn.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

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Respectfully submitted,

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